

CLAIMS

1. A test kit for detecting periodontal disease in a patient by analysing a sample from the oral cavity of the patient, wherein said kit at least comprises:
  - a first detection assay for detecting a first substance originating from bacteria, and
  - a second detection assay for detecting a second substance originating from the immune or inflammatory system of the patient.
2. A test kit according to claim 1, wherein said first detection assay comprises at least a first affinity ligand having a binding site for binding said first substance originating from bacteria, and
- said second detection assay comprises at least a second affinity ligand having binding site for binding said second substance originating from the immune or inflammatory system of the patient.
3. A test kit according to claim 1 or 2, wherein said first substance is a bacterial virulence product.
4. A test kit according to claim 3, wherein said first substance is an enzyme.
5. A test kit according to claim 4, wherein said enzyme is a protease.
6. A test kit according to claim 5, wherein said protease is selected from the group consisting of arg-gingipain from *Porphyromonas gingivalis* and a 48 kDa protease from *Bacteroides forsythus*.
7. A test kit according to claim 3, wherein said first substance is a toxin.
8. A test kit according to claim 7, wherein said toxin is a leukotoxin from *Actinobacillus actinomycetem-comitans*.
9. A test kit according to any of the preceding claims, wherein said second substance is a leukocyte product.

10. A test kit according to claim 9, wherein said leukocyte product is a natural serine protease.

11. A test kit according to claim 10, wherein said natural serine protease is a human neutrophil elastase.

5 12. A test kit according to any of the claims 1-8, wherein said second substance is a cytokine.

13. A test kit according to claim 12, wherein said cytokine is an interleukin.

10 14. A test kit according to claim 13, wherein said interleukin is chosen from among interleukin-1 $\beta$ , interleukin-6 and interleukin-8.

15. A test kit according to claim 12, wherein said cytokine is an inflammatory mediator.

15 16. A test kit according to claim 15, wherein said inflammatory mediator is selected from the group consisting of tumour necrosis factor- $\alpha$  and prostaglandin E<sub>2</sub>.

17. A test kit according to any of the claims 2 to 16, wherein said first affinity ligand is a first antibody exhibiting selective binding of said first substance  
20 and said second affinity ligand is a second antibody exhibiting selective binding of said second substance.

18. A test kit according to claim 17, wherein each of said first and second detection assays provides an immunochromatographic assay.

25 19. A test kit according to any of the preceding claims, further comprising a support provided with a sample reservoir for receiving said sample, wherein said first and second detection assays are arranged on said support in contact with said sample reservoir, directly  
30 or via a removably arranged separating means which separates said sample reservoir from said detection assays.

20. A test kit according to any of the preceding claims, further comprising additional buffers for dilution and adaptation of said sample for said detection as-  
35 says.

21. A test kit according to claim 20, further comprising a buffer reservoir separate from said sample reservoir.

22. A test kit according to any of the preceding  
5 claims, further comprising at least one sampling device for obtaining said sample.

23. The use of a test kit according to any of the preceding claims for detecting periodontal disease.

24. A method for diagnosing periodontal diseases  
10 and/or predicting the risk for progress of said diseases, said method comprising:

analyzing a sample from the oral cavity of a patient for the presence of at least a first substance originating from bacteria and the presence of a second  
15 substance originating from the immune or inflammatory system of the patient.

25. A method according to claim 24, wherein said first substance is a bacterial virulence product.

26. A method according to claims 25, wherein said  
20 first substance is an enzyme.

27. A method according to claim 26, wherein said enzyme is a protease.

28. A method according to claim 27, wherein said protease is selected from the group consisting of arg-  
25 gingipain from Porphyromonas gingivalis and a 48 kDa protease from Bacteroides forsythus.

29. A method according to claim 25, wherein said first substance is a toxin.

30. A method according to claim 29, wherein said  
30 toxin is a leukotoxin from Actinobacillus actinomycetemcomitans.

31. A method according to any of the claims 24-30, wherein said second substance is a leukocyte product.

32. A method according to claim 30, wherein said  
35 leukocyte product is a natural serine protease.

33. A method according to claim 32, wherein said natural serine protease is a human neutrophil elastase.

34. A method according to any of the claims 24-30, wherein said second substance is a cytokine.

35. A method according to claim 36, wherein said cytokine is an interleukin.

5       36. A method according to claim 35, wherein said interleukin is chosen from among interleukin-1 $\beta$ , interleukin-6 and interleukin-8.

37. A method according to claim 36, wherein said cytokine is an inflammatory mediator.

10       38. A method according to claim 37, wherein said inflammatory mediator is selected from the group consisting of tumour necrosis factor- $\alpha$  and prostaglandin E<sub>2</sub>.

15       39. A method according to any of the claims 24-38, wherein said analyzing comprises analyzing said sample with a first method that selectively detects the presence of said first substance and a second method that selectively detects the presence of said second substance.

20       40. A method according to claim 39, wherein said first method comprises using a first antibody exhibiting selective binding of said first substance and wherein said second method comprises using a second antibody exhibiting selective binding of said second substance.

25       41. A method according to claim 40, wherein at least one of said first and second methods comprises using an immunochromatographic assay.